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(20)

No. 06-1249

Supreme Court, U.S.
FILED
AUG 14 2008
OFFICE OF THE CLERK

IN THE
Supreme Court of the United States

WYETH,
Petitioner,
v.
DIANE LEVINE,
Respondent.

On Writ of Certiorari to the
Vermont Supreme Court

BRIEF OF *AMICI CURIAE* FORMER FDA COMMISSIONERS DR. DONALD KENNEDY AND DR. DAVID A. KESSLER IN SUPPORT OF RESPONDENT

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August 14, 2008

TABLE OF CONTENTS

TABLE OF AUTHORITIES. ii

INTEREST OF *AMICI CURIAE*. 1

SUMMARY OF ARGUMENT. 4

ARGUMENT. 7

I. State Failure-To-Warn Litigation Does Not Conflict with The FDA's Authority Over Drug Labeling. 7

II. The FDA's Post-Approval Monitoring System Cannot, On Its Own, Safeguard Public Health. 17

III. Congress's Refusal to Preempt Failure-To-Warn Cases Counsels Against Finding Implied Preemption. 24

CONCLUSION. 30

TABLE OF AUTHORITIES

Cases	Pages
Bates v. Dow Agrosciences L.L.C., 544 U.S. 431 (2005)	12, 25
Blood Balm v. Cooper, 10 S.E. 118 (Ga. 1889)	25
Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141 (1989)	25
Brunswig v. White, 8 S.W. 85 (Tex. 1888)	25
California Federal Sav. & Loan Ass'n v. Guerra, 479 U.S. 272 (1987)	28
Campbell v. Stamper Drug Co., 277 P. 770 (Colo. 1929)	26
Feldman v. Lederle Labs., 592 A.2d 1176 (N.J. 1991)	14
Halloran v. Parke, Davis & Co., 245 A.D. 727 (N.Y. App. Div. 1935)	25
Henry v. Judge & Dolph Drug Co., 245 S.W. 358 (Mo. Ct. App. 1922)	25
Howes v. Rose, 42 N.E. 303 (Ind. App. 1895)	25
Geier v. American Honda Motor Co., 529 U.S. 861 (2000)	30

In re Vioxx Products Liability Litig.,
501 F. Supp. 2d 776 (E.D. La. 2007). 15

In re Zyprexa Products Liability Litig.,
489 F. Supp. 2d 230 (E.D.N.Y. 2007). 10, 21

Levine v. Wyeth, 2006 VT 107 (2006). 12, 13

McDarby v. Merck, 949 A.2d 223
(N.J. App. Div. 2008). 11, 15, 16, 18, 21, 22

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). 26

Moehlenbrock v. Parke, Davis & Co.,
169 N.W. 541 (Minn. 1918). 25

Parke-Davis & Co. v. Stromsodt,
411 F.2d 1390 (8th Cir. 1969). 25

Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008). . . . 26

Schafer v. American Cyanamid Co.,
20 F.3d 1 (1st Cir. 1994). 26

Sprietsma v. Mercury Marine, 537 U.S. 51 (2002). . 30

Swift & Co. v. Wickham, 382 U.S. 111 (1965). 28

Tatum v. Schering Corp.,
795 F.2d 925 (11th Cir. 1986). 21

Thomas v. Winchester, 6 N.Y. 397 (1852). 5, 25

Tucker v. SmithKline Beecham Corp.,
2008 U.S. Dist. LEXIS 55919 (S.D. Ind. 2008). . 14

United States v. Dotterweich, 320 U.S. 227 (1943). . 2

United States v. Lane Labs-USA, Inc.,
427 F.3d 219 (3d Cir. 2005). 27

United States v. Sullivan, 332 U.S. 689 (1948). . 2, 17

Valmas Drug Co. v. Smoots, 269 F. 356
(6th Cir. 1920). 25

Wright v. Carter Products,
244 F.2d 53 (2d Cir. 1957). 25

Statutes

Food, Drug, and Cosmetic Act

21 U.S.C. § 352(a), (f), (j). 14
21 U.S.C. § 355. 8
21 U.S.C. § 355(b)(1)(F). 7
21 U.S.C. § 355(d). 7
21 U.S.C. § 360k. 26
21 U.S.C. § 379r(a), (e). 27
21 U.S.C. § 505(o)(4). 16
21 U.S.C. § 505(o)(4)(H). 16
21 U.S.C. § 505(o)(4)(I). 28

National Childhood Vaccine Injury Act

42 U.S.C. §§ 300aa-1, *et seq*. 26

Drug Amendments of 1962

Pub. L. 87-781, 76 Stat. 780, 793. 28

Legislative Materials

H.R. Rep. No. 110-225 (2007). 29
153 Cong. Rec. S11,831 (Sept. 20, 2007). 29

Regulations and Regulatory Statements:

21 C.F.R. § 201.57(c)(6)(i). 9, 19, 28
21 C.F.R. § 201.80. 14
21 C.F.R. § 201.80(e). 9, 19, 28
21 C.F.R. § 310.305. 22
21 C.F.R. § 312.32(d)(3). 22
21 C.F.R. § 314.70. 28
21 C.F.R. § 314.70(b). 9
21 C.F.R. § 314.70(c). 9, 14
21 C.F.R. § 314.70(c)(6)(A)-(D). 9
21 C.F.R. § 314.70(c)(7). 15
21 C.F.R. § 610.12. 28
30 Fed. Reg. 993 (1964). 10
44 Fed. Reg. 37,434 (1979). 10, 11
59 Fed. Reg. 3,944 (1994). 11
63 Fed. Reg. 66,378 (1998). 11

Miscellaneous

Alex Berenson, *Eli Lilly Said to Play Down Risk of Top Pill*, N.Y. Times, Dec. 17, 2007. . . . . 15, 22

Alex Berenson, *Drug Files Show Maker Promoted Unapproved Use*, N.Y. Times, Dec. 18, 2006. 21

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Margaret A. Berger & Aaron D. Twerski, *From the Wrong End of a Telescope: A Response to Professor Bernstein*, 104 Mich. L. Rev. 1983 (2006)..... 15

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Institute of Medicine, *The Future of Drug Safety, Promoting and Protecting the Health of the Public* (2006). 19, 24

Donald Kennedy, *Misbegotten Preemptions*, 320 Science 585 (May 2, 2008). 4

Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308 (2007). 12, 13

David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Effort to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461 (2008). 4, 8, 14, 15, 16, 17, 20, 22

Thomas O. McGarity, *The Preemption War* (Yale Univ. Press 2008). 11

Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1 (1973). 8, 9

David B. Ross, *The FDA and the Case of Ketek*, 356 New Eng. J. of Med. 1601 (2007). 12

Stephanie Saul, *Gimme an RX! Cheerleaders Pep Up Drug Sales, N.Y. Times*, Nov. 28, 2005. 21

Stephanie Saul, *Drug Makes Pay for Lunch as they Pitch*, N.Y. Times, July 28, 2006. 21

Stephanie Saul, *Doctor Says Drug Maker Tried to Quash His Criticism of Avandia*, N.Y. Times, June 7, 2007. 21

INTEREST OF *AMICI CURIAE*[1]

This brief in support of respondent is filed on behalf of Dr. Donald Kennedy and Dr. David Kessler, each of whom served as Commissioner of Food and Drugs at the Food and Drug Administration (FDA).

Dr. Donald Kennedy, a biologist, served as FDA Commissioner from 1977 to 1979. Dr. Kennedy then returned to Stanford University, where he had previously been a member of the faculty. From 1980 to 1992, Dr. Kennedy served as President of Stanford University. When he stepped down he returned to the faculty and is currently a professor emeritus. From 2000 until 2008, Dr. Kennedy also served as editor-in-chief of *Science*, the weekly magazine published by the American Association for the Advancement of Science.

Dr. David A. Kessler was appointed by President George H.W. Bush in 1990 to serve as FDA Commissioner. Dr. Kessler was reappointed to that position by President William J. Clinton. After serving as Commissioner for seven years, Dr. Kessler left the FDA in 1997 to join the Yale School of Medicine as Dean, a position he held until 2003. From 2003

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[1] Pursuant to Rule 37.6 of the Rules of the Supreme Court of the United States, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae* or their counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

through 2007, Dr. Kessler served as Dean and Vice-Chancellor of the University of California, San Francisco, Medical School. Dr. Kessler remains on the medical school faculty.

Amici file this brief because the pro-preemption position urged by petitioner and the United States threatens to undermine, not advance, the underlying goal of our nation's drug safety laws, which is "to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696 (1948); *see also United States v. Dotterweich*, 320 U.S. 277, 282 (1943). The nation's drug safety laws have never placed the responsibility for drug safety solely on FDA. To the contrary, they place primary responsibility for safety squarely on the shoulders of drug manufacturers. To be sure, FDA also plays an important role; it oversees, and when necessary compels, compliance with safety standards. But the ultimate responsibility remains with the manufacturer. *Amici* submit that the pro-preemption arguments pressed by petitioner and the United States turn that understanding upside down, relieving manufacturers of front-line responsibility for the safety of their drugs and handing that job to the FDA.

Failure-to-warn litigation has always played an important role in ensuring that manufacturers bear responsibility for the safety of their drugs. Failure-to-warn litigation preceded the enactment of the first federal drug safety law, the Federal Pure Food and Drug Act of 1906, and it has been a complement to federal enforcement of drug safety laws throughout the history of FDA and its predecessor agencies. Indeed,

until 2002, failure-to-warn litigation was seen by both Congress and FDA as an important adjunct to federal regulation.

Congress has been particularly attentive to the federalism issues relating to FDA regulation of drugs and medical devices, but has never seen fit to preempt state failure-to-warn claims for drugs. Congress has, over the years, provided limited preemption of state-law claims for medical devices specifically approved by FDA, over-the-counter drugs, and vaccines. Although Congress has repeatedly revisited the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), including a significant overhaul in the 2007 Food and Drug Administration Amendments Act, Congress has never given drug companies the immunity from liability they covet and now seek from this Court.

Congress's unwillingness to cut off state failure-to-warn litigation is in keeping with FDA's longstanding judgment that this litigation complements the agency's regulatory and enforcement activities. At least until 2002, FDA consistently took the position that state failure-to-warn litigation enhances consumer safety by serving three critical functions:

* **Information:** State failure-to warn litigation augments the FDA's post-approval surveillance of drug safety by uncovering hazards unknown to FDA and by providing information about those hazards to the agency, physicians and patients;

* **Incentives:** State failure-to-warn litigation provides powerful incentives for drug companies to

disclose safety risks with their products to FDA, physicians and patients as soon as evidence of a serious hazard becomes available; and

* **Compensation:** State failure-to-warn litigation serves a compensatory justice function unaddressed by federal law (except for vaccines).

For these reasons, *amici* submit that the absence of a robust system of state failure-to-warn litigation would severely compromise FDA's ability "to protect consumers from dangerous products." Both Dr. Kennedy and Dr. Kessler have set forth their views on this topic; Dr. Kennedy in an editorial, *Misbegotten Preemptions*, 320 Science 585 (May 2, 2008), and Dr. Kessler in a law review article, David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Effort to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461 (2008) (hereinafter Kessler & Vladeck).

SUMMARY OF ARGUMENT

Troubled by the public health implications of petitioner's and the United States' positions in this case, *amici* file this brief to amplify three points that may not stand out in respondent's more comprehensive treatment of the issues:

First, there is no conflict between federal and state law over the contents of a drug's label, or a manufacturer's duty to warn physicians, patients, and FDA of emerging safety hazards. To be sure, the FDCA gives FDA substantial authority over the labeling and promotion of pharmaceutical products.

But nothing in the FDCA, or in FDA's implementing regulations, relieves a manufacturer of its duty to warn physicians and patients of emerging safety risks as soon as that information becomes available. This duty predates by decades the advent of federal regulation of drugs. *See, e.g., Thomas v. Winchester*, 6 N.Y. 397 (1852). FDA's longstanding regulations make clear that a drug company has a duty to modify labeling without delay when hazards emerge with one of its drugs. The regulations expressly authorize the company to make labeling changes, and take other steps to inform physicians and patients of emerging risks, without advance approval from the agency.

Moreover, failure-to-warn litigation does not challenge *FDA's* decisions about labels; rather, it challenges a *company*'s failure to alert physicians and patients to risks that were unknown or poorly understood when FDA approved the drug's label, but were evident to the company at the time the plaintiff sustained injury. Litigation of that sort complements, not undercuts, FDA's job of protecting consumers from dangerous drugs.

Second, petitioner's argument depends on two related myths: *first*, that FDA has timely access to safety information and to resources that enable it to engage in the day-by-day monitoring of the safety profile of all of the thousands of drugs on the market; and *second*, that FDA's capacity to keep abreast of emerging safety information — even after a drug moves from pre-approval clinical testing to post-approval use in thousands or millions of patients — is equal to that of the drug's manufacturer. Neither of

these myths is true today; neither was true when Dr. Kennedy and Dr. Kessler headed FDA; and neither will be true tomorrow. The simple fact is that drug companies have far superior information-gathering tools about the safety profile of the drugs they sell, while FDA's tools to keep track of safety hazards post-approval are imperfect at best. For this reason, FDA has always imposed a duty on manufacturers that parallels and reinforces the same duty state law imposes — namely, the duty to disclose emerging safety information to FDA and physicians as soon as it becomes available. Contrary to petitioner's claim, there is no tension between federal and state law; the requirements imposed by federal regulations and state duty-to-warn laws are parallel in all material respects.

Third, the background history of state failure-to-warn litigation over drug products, coupled with Congress's unwillingness to include an express preemption provision in the drug provisions of the FDCA, counsel strongly against finding implied preemption in this case. Congress's refusal to give the pharmaceutical industry the liability protection it covets reflects Congress's judgment that, whatever tensions might theoretically exist between the FDCA and application of state law, the benefits to consumer protection derived from state failure-to-warn litigation exceed the costs. Leaving Congress's decision undisturbed makes particular sense here, where petitioner's and FDA's claims of conflict between state and federal law are not based on hard evidence of actual conflict but instead rest only on predictive judgments unanchored to history.

ARGUMENT

I. State Failure-to-Warn Litigation Does Not Conflict With FDA's Authority Over Drug Labeling.

Petitioner's implied preemption argument rests on the false premise that failure-to-warn litigation seeks to supplant FDA as final decision-maker as to the content of drug labeling. That is not so. The FDCA gives FDA substantial authority over drug labeling. 21 U.S.C. § 355(d). Failure-to-warn litigation does not undercut FDA's authority over drug labeling; rather, it challenges the *company's* failure to warn doctors and patients about risks that were unknown or poorly understood at the time FDA approved the drug and the label, but were evident to the company at the time the plaintiff sustained injury.

The emergence of safety hazards that were unknown or not well understood at the time of a drug's approval is commonplace. FDA's approval process is not a warrant of the drug's absolute safety, but is an assessment of whether the drug's benefits outweigh its potential risks based on the evidence available to FDA at the time.

To obtain approval for a new drug, a manufacturer must submit a new drug application (NDA) for the agency's review. 21 U.S.C. § 355; *see generally* Kessler & Vladeck, 96 Geo. L.J. 470-73. The NDA must include, among other things, full results of all clinical studies performed on human subjects. Pre-market human studies generally involve only a few thousand

subjects and last only a year or so. To control for conditions that might distort the study's findings, subjects who take other drugs or have other diseases or infirmities are excluded. *See* Kessler & Vladeck, 96 Geo. L.J. at 471. Because of these limitations, pre-approval testing is generally incapable of detecting adverse effects that have long latency periods, result from drug interactions, occur infrequently, or affect sub-populations excluded from or not adequately represented in the clinical studies (for example, the elderly, ethnic minorities, and pregnant women). *Id.* Moreover, FDA's assessment of risks-versus-benefits is generally done population-wide, not sub-group by sub-group, because there are rarely enough clinical trial participants in a sub-group to permit that degree of refined analysis. *Id.* For these reasons, FDA approval of a drug is no guarantee that the drug will not cause serious adverse effects even if properly used for its approved purposes.[2]

When FDA approves a new drug, it also approves the precise final version of the drug's label. 21 U.S.C. § 355(b)(1)(F). Because the NDA process is intended to provide FDA with all then-existing information about the drug's risks, the label approved by the FDA represents the agency's best judgment about risks that warrant disclosure and those that do not.

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[2] Professor and former FDA General Counsel Richard A. Merrill once quipped, "All consumers of prescription drugs serve as guinea pigs for the pharmaceutical industry." *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 20 (1973).

But the label's content is not set in stone. Once a drug enters the marketplace, unanticipated adverse effects begin to emerge and the drug's labeling needs to be revised. Generally labeling changes are initiated by the manufacturer and subject to FDA pre-approval. 21 C.F.R. § 314.70(b). But there are exceptions. The most important exception is that "labeling *shall* be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug[.]" 21 C.F.R. § 201.80(e) (emphasis added); *see also id.* § 201.57(c)(6)(i) (imposing requirement in slightly different language). Statements that may be added to labels without prior FDA approval are those:

> [A] To add or strengthen a contraindication or warning, precaution, or adverse reaction; [B] To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage; [C] To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the product; [or D] To delete false, misleading, or unsupported indications for use or claims of effectiveness.

21 C.F.R. § 314.70(c)(6)(iii)(A)-(D).

Once a manufacturer adds a warning, it must then promptly inform FDA of the change being effected (or CBE) in a supplemental NDA, which FDA reviews after-the-fact. *Id.* § 314.70(c). This "safety valve" option enables a manufacturer to provide physicians, health care professionals, and patients up-to-date safety information without the need to secure FDA's

advance approval. And FDA has long made clear that its labeling rules are no obstacle to a manufacturer providing safety information to doctors and patients though labeling, advertising, "Dear Doctor" letters, and other avenues of communication as soon as the manufacturer discovers risks not mentioned on the label. 44 Fed. Reg. 37,434, 37,447 (June 26, 1979); 30 Fed. Reg. 993 (Jan. 30, 1965).[3]

As noted, failure-to-warn litigation does not challenge FDA's authority over drug labeling, but instead challenges a company's failure to take measures to notify physicians and patients when safety problems emerge with a drug. These cases seek money damages for injuries caused by a lack of an adequate warning, not injunctions or other court decrees to force labeling changes.[4]

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[3] Although petitioner focuses on labeling, failure-to-warn cases typically challenge the drug company's failure to *warn*, not failure to revise *labeling*. A drug company can discharge its duty to warn through other means, including, for example, "Dear Doctor" letters, information distributed by the company's sales-force, advertising and promotional materials, and other communications with doctors and patients. *See, e.g., In re Zyprexa Products Liability Litigation*, 489 F.Supp. 2d 230, 248-60 (E.D.N.Y. 2007) (considering but rejecting company's defense that prescribing physicians knew of the link between Zyprexa and diabetes from the company's sales representatives even before association appeared on the drug's label).

[4] Prior to 2002, FDA repeatedly made clear that

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In failure-to-warn litigation, the plaintiff alleges that the drug company failed adequately to warn of risks that were evident to the company, but undisclosed, at the time the plaintiff was injured. Almost invariably, the risks at issue were unknown or poorly understood at the time FDA approved the drug and its label.[5] In a typical case, a judgment in the plaintiff's favor may result in the company deciding

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[4](...continued)
agency labeling decisions did not preempt tort liability. *See, e.g.*, 44 Fed. Reg. at 37,447 (FDA labeling decisions do not "influence civil tort liability of the manufacturer."); 59 Fed Reg. 3,944, 3,948 (Jan. 27, 1994) (recognizing that "product liability plays an important role in consumer protection," in notice proposing rules to protect the identities of individuals reporting adverse drug reactions); 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998) (observing that FDA labeling "regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements," in FDA's final guidance on prescription drug labeling).

[5] Many of the recent failure-to-warn cases, including those involving Vioxx, Ortho Evra, Propulsid, Zyprexa, and Avandia, allege that the drug's manufacturer withheld important safety data from FDA. *See infra* n.11. The Vioxx cases underscore that FDA did not understand the cardiovascular risks posed by the drug at the time of approval and that Merck withheld information relating to the drug's cardiovascular risks from FDA to avoid a stronger warning on the label. *See* Thomas O. McGarity, *The Preemption War* 1-17 (Yale Univ. Press 2008) (detailing Vioxx's regulatory history); *McDarby v. Merck*, 949 A.2d 223, 231-47 (N.J. App. Div. 2008) (same).

that the risk is sufficiently common or grave to warrant a warning. The company would then ask FDA to approve a warning change or add a warning to the label and then seek FDA's approval. It is also possible that, regardless of the case's outcome, safety information disclosed as a result of the litigation might prompt FDA to decide that a stronger warning is appropriate and to initiate discussions with the company over a labeling change. *See Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 451 (2005) (observing that state damages litigation "may aid in the exposure of new dangers associated with" the product and prompt the agency to "decide that revised labels are required in light of the new information that has been brought to its attention.").[6]

Notwithstanding Wyeth's efforts to paint this case otherwise, this is a garden variety failure-to-warn case. Diana Levine's injury was caused by the intravenous administration of Wyeth's drug Phenergan through the "direct IV" or "IV push" method, whereby Phenergan is supposed to be injected directly into the patient's *vein*, but was instead injected into her *artery*. *Levine v. Wyeth*, 2006 VT 107 (2006). The evidence showed that Wyeth had known for decades that the IV push method of administration can result in inadvertent contact

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[6] This happens with some regularity with respect to drug labeling. *See, e.g.*, Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 310 (2007) (citing examples); David B. Ross, *The FDA and the Case of Ketek*, 356 New Eng. J. of Med. 1601 (2007).

between the drug and the patient's artery. When the drug comes in contact with an artery, the artery can die and necrosis, gangrene and amputation can result. Ms. Levine was forced to have her arm amputated due to the administration of Phenergan through the IV push method. *Id.* at ¶2. The evidence showed that Wyeth failed to instruct physicians not to use push IV, either in its labeling or otherwise. *Id.* at ¶3. Indeed, Wyeth argued that adding the warning Ms. Levine claimed was lacking — an explicit direction to physicians not to use IV push — "would have harmed patients by eliminating the IV push as an option for administering Phenergan." *Id.* at ¶23; *see also id.* at ¶3.

To be sure, Wyeth argues that implied preemption is warranted here because the FDA considered and rejected the specific warning Ms. Levine claims was lacking. But both the trial court and the Vermont Supreme Court rejected that argument as a matter of fact. *Id.* at ¶¶21-23. The Vermont Supreme Court acknowledged that, during the over fifty years that Phenergan has been approved for use, Wyeth and FDA twice discussed modifications to the label. *Id.* But the Vermont Supreme Court found no evidence that (a) FDA had ever considered and approved the safety of the IV push method of administration, (b) FDA had determined that Ms. Levine's claim was scientifically unsubstantiated, (c) FDA intended to prohibit Wyeth from strengthening its label to warn physicians against using the IV push method, or (d) FDA made an affirmative decision to preserve the IV push method of administration. *Id.* at ¶23. Wyeth's arguments to the contrary are not based on the record.

Wyeth's efforts to obscure the real facts of this case are not surprising. The reality is that few, if any, cases fall into the fact pattern that Wyeth alleges occurred here. Neither Wyeth nor the United States point to any actual man-bites-dog cases where a company (which is trying to sell its drug) wants a *stronger* label than FDA does, and FDA (which is trying to safeguard the public health) *resists* the change.[7] In case after

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[7] Even if such a case arose, the company still may strengthen its label if, in its view, a stronger warning is warranted. As one court recently noted, "Although the FDA might later disapprove of a label strengthened pursuant to 21 C.F.R. § 314.70(c) and § 201.80, the FDA's power to disapprove does not make the manufacturer's voluntarily strengthened label a violation of federal law." *Tucker v. SmithKline Beecham Corp.*, 2008 U.S. Dist. LEXIS 55919 * 8 (S.D. Ind. 2008) (citations omitted). After all, "FDA might do nothing, thus giving effect to the change." *Id.* Even if FDA disapproves the revised label, "the FDA's disapproval is not retroactive[]" and the manufacturer may remove the warning. *Id.; see also* 21 C.F.R. § 314.70(c)(7). In such a case, the manufacturer would have an airtight regulatory compliance defense in a tort suit, but if the company never seeks to change the label, it should not be able to use the approval requirement as a liability shield. And if the manufacturer retains the label even after FDA's disapproval, FDA can, in theory, bring a "misbranding" action in court, and a jury would decide the question. *Tucker*, at * 8 & n.3; 21 U.S.C. § 352(a), (f), (j). To *amici*'s knowledge, FDA has never brought a misbranding action under these circumstances. *Cf. Feldman v. Lederle Labs.*, 592 A.2d 1176, 1193 (N.J. 1991) ("for the FDA to have prevented a drug manufacturer from warning the public of

(continued...)

case, companies *fight* stronger warnings that might discourage doctors from prescribing their drugs and thereby undermine the drugs' profitability.[8] For instance, it took FDA over a year to force Merck, the manufacturer of Vioxx, to add a statement about Vioxx's cardiovascular risks to the drug's label. Merck fought hard because it had determined that a "warning" rather than a "precaution" on Vioxx's label could lead to a 50% reduction in Vioxx's sales.[9] During the year-long negotiations between Merck and FDA, no change was made to Vioxx's label, and in the end, the FDA accepted a compromise: The statement about cardiovascular risk was added to the "precaution"

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[7](...continued)
a newly-discovered danger . . . 'would seem anomalous.'") (citation omitted).

[8] *See, e.g.*, Kessler & Vladeck, 96 Geo. L. J. at 480 (and authorities cited therein); *McDarby v. Merck*, 949 A.2d at 238-48 (account of dispute between Merck and FDA over Vioxx's label); *In re Vioxx Products Liability Litigation*, 501 F. Supp. 2d 776, 779, 783 (E.D. La. 2007) (same); Margaret A. Berger & Aaron D. Twerski, *From the Wrong End of a Telescope: A Response to Professor David Bernstein*, 104 Mich. L. Rev. 1983, 1987-88 (2006) (recounting Sandoz's effort to avoid labeling changes for its lactation-suppressing drug Parlodel, which it ultimately withdrew from the market).

[9] *McDarby v. Merck*, 949 A.2d at 241. *See also* Alex Berenson, *Eli Lilly Said to Play Down Risk of Top Pill*, N.Y. Times, Dec. 17, 2006, at A1 (discussing Eli Lilly's effort to avoid a warning on Zyprexa, its best selling schizophrenia medication, for diabetes risk).

section of the label as Merck urged, not to the "warning" section, notwithstanding FDA's judgment that a warning was appropriate. *See* Kessler & Vladeck, 96 Geo. L.J. at 480 & n.82 (citing congressional testimony of FDA officials acknowledging that FDA did not have the power to compel Merck to add a warning to Vioxx's label).[10]

As is clear, contrary to the submissions of petitioner and the United States, there is no conflict between the application of state failure-to-warn litigation and FDA's authority over drug labeling. These regimes have co-existed without friction for the entire life-span of the agency. Nothing in this case or in the reasoned decision of the Vermont Supreme Court threatens FDA's ability to control drug labeling. For that reason the judgment below should be affirmed.

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[10] The 2007 Amendments to the FDCA give FDA, for the first time, the authority to compel a manufacturer to add warnings to a drug's label. 21 U.S.C. § 505(o)(4). Even so, this power is significantly circumscribed and cannot, as an ordinary matter, be used by the agency unilaterally or immediately. FDA may "accelerate" the process when "a labeling change is necessary to protect the public health." But the agency may not bypass the process set up in the Act. *Id.* at § 505(o)(4)(H); *See also* Kessler & Vladeck, 96 Geo. L. J. at 467-68 n.24.

II. FDA's Post-Approval Monitoring System Cannot, On Its Own, Adequately Safeguard Public Health.

The pro-preemption arguments advanced by petitioner and the United States fail for another reason: They significantly overstate FDA's ability to police the marketplace on its own, without the backstop of state failure-to-warn litigation. The question before this Court is whether state failure-to-warn litigation jeopardizes the fulfillment of the FDCA's goal, namely, "to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. at 696.

The short answer to that question is "no." State failure-to-warn litigation plays an indispensable role in achieving that goal. The fundamental problem FDA faces is that, by necessity, drugs are approved on the basis of less-than-perfect knowledge. Risks that are rare, have long latency periods, result from drug interactions, or have adverse impacts on sub-populations often go undetected in clinical testing. Despite FDA's recent claims, the agency cannot single-handedly perform the Herculean job of monitoring the safety of every one of the 11,000 or so drugs on the market. Until 2002, FDA recognized that failure-to-warn litigation served as an important backstop to the agency's own efforts. *See* Kessler & Vladeck, 96 Geo. L.J. at 483-86.

Nonetheless, petitioner and the United States paint a portrait of FDA that is unrealistic. Contrary to their claims, FDA does not have timely access to safety

information and other resources to enable it to engage in a day-by-day monitoring of the safety profile of every one of the thousands of drugs on the market (not to mention medical devices, food products, blood products and other biologics, and the hundreds of other consumer products FDA regulates), let alone the capacity to monitor the safety profile of an individual drug that is even remotely equivalent to that of the drug's manufacturer. *Id.* There are several reasons why the Court should be skeptical of petitioner's and the United States' arguments about FDA's ability to police the market on its own.

First, these arguments are called into doubt by recent history. In the past few years, FDA has faced a flood of high-profile regulatory failures with recently approved drugs, including pain medications Vioxx, Celebrex, and Bextra, the diabetes drugs Avandia and Rezulin, and the heartburn drug Propulsid. In each of these cases, there was a substantial delay between when the manufacturer had "reasonable evidence of an association of a serious hazard" with its drug (*see* 21 C.F.R. §§ 201.57(c)(6)(i), 201.80(e)), and when the manufacturer provided that information to FDA or took action to warn physicians or patients. *See id.* (a manufacturer *shall* revise labeling once it has reasonable evidence of an association).[11]

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[11] *See, e.g., Darby v. Merck*, 949 A.2d at 241-44 (pointing out Merck's delays in reporting information about Vioxx's cardiovascular risks to FDA); Alex Berenson & Gardiner Harris, *Pfizer Says 1999 Trials Revealed Risks With Celebrex*. N.Y. Times, Feb. 1, 2005, A1 (reporting that

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Second, FDA's post-approval surveillance resources do not match FDA's rhetoric. Both the Institute of Medicine (IOM) and the Government Accountability Office (GAO) have issued reports highly critical of FDA's surveillance programs, with the IOM concluding that the programs detect at most a "small fraction of all adverse effects of drugs."[12] Detection is

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[11](...continued)
Pfizer acknowledged withholding from FDA for two years study showing serious cardiovascular risk with Celebrex); Gardiner Harris and Eric Koli, *Lucrative Drug, Danger Signals and the FDA*, N.Y. Times, June 10, 2005 (discussing delays in reporting safety information on heartburn medication Propulsid); Denise Grady, *FDA Reviews Accusations About Diabetes Drug*, N.Y, Times, Mar. 16, 2000 (reporting that FDA records showed that company failed to submit safety data on diabetes drug Rezulin); Gardiner Harris & Alex Berenson, *Drug Makers Near Old Goal: A Legal Shield*, N.Y. Times, Apr. 6, 2008, A1 (reporting that documents obtained during litigation showed that Johnson & Johnson delayed informing the FDA for years that Ortho Evra, a birth control patch, delivered far more estrogen than it claimed, increasing the risks of blood clots and strokes, and noting that "[i]n the last decade, suits over Zyprexa, the withdrawn pain pill Vioxx, the withdrawn diabetes medicine Rezulin, the withdrawn heartburn medicine Propulsid and several antidepressants have shown that companies played down the risks of their medicines.").

[12] IOM, *The Future of Drug Safety, Promoting and Protecting the Health of the Public* 51, 53 (2006) (hereinafter "IOM Report"); GAO, *Drug Safety: Improvement Needed in*
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not the only problem. As the IOM put it, "[t]he existing regulatory framework is structured around the premarketing testing process; few tools are available for addressing postmarketing issues, short of the blunt instruments available to respond to clear-cut adulteration and misbranding." IOM Report at 153. Even if these programs are strengthened, top down FDA surveillance is no substitute for failure-to-warn litigation, which provides FDA, doctors and patients with safety information that is otherwise unavailable to the agency.

Third, petitioner's argument assumes that FDA and a drug manufacturer have equal access to information about emerging safety hazards with the manufacturer's drug. That is not the case. Manufacturers have superior resources that are committed to overseeing the safety of the drugs they market. As a result, manufacturers invariably get safety information before the FDA does and have access to information that is not available to FDA.

This fact should not be surprising. Drug companies have dedicated sales forces (detailmen) who visit with doctors quite frequently (weekly or, at times, more

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FDA's Postmarket Decision-Making and Oversight Process 18 (2006) (hereinafter "GAO Drug Safety"). Although the 2007 Amendments bolster FDA's authority in this area, the reforms available under the Amendments will take considerable time to implement and their success is uncertain. Kessler & Vladeck, 96 Geo. L.J. at 489-91.

often). Detailmen serve as an early warning system when problems begin to emerge with a drug and as a means by which drug companies disseminate risk information to doctors.[13] Drug companies also sponsor trials of approved drugs to see if they are effective for new uses not approved by the FDA. For instance, a study on Vioxx in Alzheimer's patients showed a higher incidence of cardiovascular events than did the placebo group, but Merck did not disclose the study's results to

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[13] There are an estimated 90,000 drug company sales representatives (detailmen) in the United States. *See, e.g.*, Stephanie Saul, *Gimme an Rx! Cheerleaders Pep Up Drug Sales*, N.Y. Times, Nov. 28, 2005, A1; Stephanie Saul, *Drug Makes Pay for Lunch as they Pitch*, N.Y. Times, July 28, 2006, A1; Stephanie Saul, *Doctor Says Drug Maker Tried to Quash His Criticism of Avandia*, N.Y. Times, June 7, 2007, A1 (reporting that FDA reprimanded Glaxo, the manufacturer of Avandia, for having its detailmen play down drug's risks to doctors); Alex Berenson, *Drug Files Show Maker Promoted Unapproved Use*, N.Y. Times, Dec. 18, 2006, A1 (reporting that Eli Lilly detailmen promoted Zyprexa, a powerful drug for schizophrenia and bipolar disorder, for patients who had neither illness). GAO reports that FDA lacks the resources to police effectively drug company promotional efforts. GAO, *Prescription Drugs: FDA Oversight of the Promotion of Drugs for Off-Label Uses* 6, 9, 24-26, 41-46 (July 2008). The role of detailmen has been pivotal in some failure-to-warn cases. *See, e.g., In re Zyprexa Products Liability Litigation*, 489 F. Supp. 2d at 248-60; *Tatum v. Schering Corp.*, 795 F.2d 925 (11th Cir. 1986); *McDarby v. Merck*, 949 A.2d at 248-49.

FDA for over a year.[14] And drug companies have physicians on staff or contract with physicians to evaluate the safety profile of drugs, but these evaluations are not generally shared with FDA.[15]

Thus, although each drug company has an obligation to report evidence of safety problems in patients treated with a drug, *see, e.g.*, 21 C.F.R. §§ 310.305; 312.32(d)(3), there is no corresponding obligation to report the impression of company doctors and scientists, who generally know more about the company's drug and the risks it might pose than their counterparts at the FDA. For these reasons, failure-to-warn litigation has time and again uncovered safety information that was known to the drug company but not provided to, or otherwise available to, FDA. Kessler & Vladeck, 96 Geo. L.J. 491-95 (and authorities cited therein).

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[14] *McDarby v. Merck*, 949 A.2d at 241.

[15] *See, e.g.*, Daniel Carlat, Op-Ed, *Diagnosis: Conflict of Interest*, N.Y. Times, June 13, 2007, at A21 (explaining that "[b]ecause pharmaceutical companies set much of the agenda for what doctors learn about drugs, crucial information about potential drug dangers is played down, to the detriment of patient care.") (discussing Avandia and Vioxx as examples); Alex Berenson, *Eli Lilly Said to Play Down Risk of Top Pill*, N.Y. Times, Dec. 17, 2006, A1 (reporting that emails and memos from Eli Lilly's top doctors and managers, discovered in litigation, show company's effort to play down the risk of diabetes with its blockbuster drug Zyprexa).

Fourth, even with the 2007 Amendments, the FDA faces a daunting future. A report issued in November 2007 by a blue-ribbon panel appointed by FDA concluded, "The scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the . . . regulatory system, and hence to the safety of the public." FDA Science Board, *FDA Science and Mission at Risk*: A Report of the Subcommittee on Science and Technology § 1.1 (2007) (hereinafter "FDA Science and Mission at Risk"). This conclusion echoes that of IOM, which warned that FDA "lacks the resources to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future." IOM Report at 193.

As FDA's panel observed, the agency has enormous and growing responsibilities, but Congress has essentially flat-lined its appropriations. When the FDCA was enacted in 1938, Congress gave FDA a mandate "to review and approve prior to marketing, the safety of color additives, human food additives and animal feed additives, as well as to review and approve the safety and effectiveness of new human drugs, new animal drugs, human biological products and medical devices for human use." FDA Science and Mission at Risk, § 2.1. Since 1938, Congress has enacted "125 statutes that directly impact FDA's regulatory responsibilities," by requiring "the development of implementing regulations, guidance or other types of policy, and some require the establishment of entire new regulatory programs. Virtually all require some

type of scientific knowledge or expertise for the agency to address them." *Id.*

Despite the addition of all of these requirements, Congress did not provide "an appropriation of new personnel and increased funding designed to allow adequate implementation." *Id.* Indeed, during the past two decades, the agency's funding and staffing levels have remained static. For these and other reasons, the report concludes that "[t]his reality, combined with a burgeoning industry . . . has made it increasingly impossible for the FDA to maintain its historic public health mission." *Id.; see also id.* Appendix B, Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, at B-24 – B-34.

Each of these factors undercuts the claim that FDA can, on its own, single-handedly police the safety of every drug on the market. Taken together, these factors underscore *amici*'s concern that finding state failure-to-warn cases preempted would deprive FDA of important safety information and would remove existing incentives that press drug companies to report and promptly respond to emerging safety hazards. For this reason too, the judgment below should be affirmed.

III. Congress's Refusal To Preempt Failure-To-Warn Claims Counsels Against Finding Implied Preemption.

The history of the evolution of the drug safety laws in the United States casts further doubt on petitioner's and the United States' implied preemption arguments.

After all, failure-to-warn litigation has been a constant feature of personal injury litigation in the courts of the United States since the mid-Nineteenth Century. One of the early drug liability cases, *Thomas v. Winchester*, 6 N.Y. 397, dates back to 1852. Since that time, there has been a steady procession of failure-to-warn cases involving drug products.[16]

Congress of course is presumed to have been aware of this litigation when it enacted the Federal Pure Food and Drugs Act of 1906, when it enacted the FDCA in 1938, and when it made major amendments to the FDCA in 1962, 1997 and 2007. *See, e.g., Bates*, 544 U.S. at 449-450; *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989).

But there is no need for guesswork about Congress's judgment about the federalism questions relating to pharmaceutical products. There are no fewer than

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[16] *See, e.g., Brunswig v. White*, 8 S.W. 85 (Tex. 1888); *Blood Balm v. Cooper*, 10 S.E. 118 (Ga. 1889); *cf. Howes v. Rose*, 42 N.E. 303 (Ind. App. 1895). After the passage of the 1906 Act, failure-to-warn litigation continued in the courts. *See, e.g., Moehlenbrock v. Parke, Davis & Co.*, 169 N.W. 541 (Minn. 1918); *Valmas Drug Co. v. Smoots*, 269 F. 356 (6th Cir. 1920); *Henry v. Judge & Dolph Drug Co.*, 245 S.W. 358 (Mo. Ct. App. 1922); *Campbell v. Stamper Drug Co.*, 277 P. 770 (Colo. 1929); *Halloran v. Parke, Davis & Co.*, 245 A.D. 727 (N.Y. App. Div. 1935); *Wright v. Carter Products*, 244 F.2d 53 (2d Cir. 1957); *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390, 1402 (8th Cir. 1969).

three express preemption provisions that reflect Congress's attention to the federalism issue.

One of these provisions — the preemption provision of the Medical Device Amendments of 1976, 21 U.S.C. § 360k — has been the subject of two recent decisions by this Court. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

Another statute, The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1, *et seq.*, was enacted by Congress to provide a means of resolving claims of injury as a result of vaccine administration that was less costly and more expeditious than conventional tort litigation. The Vaccine Injury Act requires that certain claims first be brought before the Vaccine Court, but permits the claimant to pursue tort litigation if disappointed with the Vaccine Court's disposition. *See generally Schafer v. American Cyanamid Co.*, 20 F.3d 1 (1st Cir. 1994) (Breyer, J.) (describing background and operation of the Act).[17]

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[17] The Vaccine Act also shows that Congress did not intend to curtail tort remedies for those injured by unsafe drugs and vaccines. Congress could have preempted vaccine claims, but instead carved them out of the general tort system, and included a back-end opt out for claimants who think that they can do better in the tort system. The Vaccine Act also demonstrates that the FDCA provides injured parties no compensatory remedies. To be sure, the FDA has brought at least one misbranding action for an

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A third provision, added by Congress in 1997 in the Food and Drug Administration Modernization Act, preempts state labeling requirements for non-prescription drugs that are "different from or in addition to" those imposed by the FDCA. The provision goes on to say that it shall not be "construed to modify or otherwise affect the liability of any person under the product liability law of any State." 21 U.S.C. § 379r(a), (e).

Congress has never seen fit to enact a preemption provision with respect to drugs. Indeed, Congress twice has explicitly declined to do so. First, in the 1962 amendments to the FDCA, which require FDA to ensure that a drug is effective as well as safe before the drug is approved, Congress made clear its intent not to preempt claims relying on state common law: "Nothing in the amendments . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Drug

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[17](...continued)
injunction and restitution against companies selling an *unapproved* drug, but the only remedy available for injured consumers is the reimbursement of the modest sums they paid for the unapproved product; tort damages are not available. *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219, 231 (3d Cir. 2005) (upholding restitution order against companies selling shark cartilage as cancer remedy).

Amendments of 1962, Pub. L. 87-781, § 202, 76 Stat. 780, 793.[18]

When Congress revisited the FDCA in 2007, drug companies hoped that it would add an express preemption provision barring tort litigation. Congress did not do so. To the contrary, Congress adopted a "rule of construction" that establishes that FDA's new authority to compel companies to make labeling changes does not alter a manufacturer's obligation "to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations)." 21 U.S.C. § 355(o)(4)(I). The references to the Code of Federal Regulation are to regulations that mandate that drug companies *shall* revise a drug's label to include a warning as soon as there is reasonable evidence of an association of a serious hazard with the drug, and may do so without FDA's advance approval. *See* 21 C.F.R. §§ 201.57(c)(6)(i); 201.80(e); 314.70; and 601.12. This

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[18] The provision's language underscores Congress's judgment not to displace state product liability law, but to preserve it. *See California Federal Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 283 n.12 (1987) (explaining anti-preemption thrust of phrase "a direct and positive conflict"); *Swift & Co. v. Wickham*, 382 U.S. 111, 132 n.3 (1965) (Douglas, J., dissenting) (same). The provision explicitly displaces *only* positive state law *only* where there is "a direct and positive conflict" between the FDCA's new effectiveness requirements and state law. Congress refrained from using broader language that might encompass other state law requirements, such as tort law.

"rule of construction" was added by the House to "clarify that nothing in this legislation or in current law is intended to preempt remedies for consumers injured by dangerous drugs." H.R. Rep. No. 110-225, at 197 (2007); *see also* 153 Cong. Rec. S11,831-34 (Sept. 20, 2007) (statement of Sen. Kennedy); *id.* at S11,834 (statement of Sen. Leahy); *id.* at S11,835 (statement of Sen. Durbin). The provision did not sit well with Members of Congress who wanted to add a preemption provision to the Act. *See, e.g., id.* at S11,836-37 (statement of Sen. Allard).

In the face of the long and unbroken history of failure-to-warn litigation over drug products, and Congress's refusal to add a preemption provision to federal law, this Court should be especially wary of taking a step that Congress has refrained from taking. There can be no question that Congress is well aware of the dynamic between state failure-to-warn litigation and FDA regulation of drug labeling. And there can be no question that Congress has decided that the two systems ought to co-exist, notwithstanding any tension that might arise, because the benefits of permitting the systems to operate in tandem outweigh any costs that might be incurred. That decision is plainly one that Congress is empowered to make.

This point takes on additional force here, because the "evidence" of the tension between FDA regulation of drugs and state failure-to-warn litigation is not simply thin, it is non-existent. Instead of coming forward with hard evidence of actual conflicts — that is, cases in which FDA's primacy over drug labeling has been compromised or even seriously threatened by

failure-to warn litigation — petitioner and the United States rely on what are at most predictive judgments that are unanchored in history. This Court's conflict preemption jurisprudence requires far more than that. *See, e.g., Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (refusing to find conflict preemption where there was no evidence that application of state law would frustrate federal interests); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 881-83 (2000) (finding conflict preemption based on an after-the-fact assessment of actual frustration of federal interests). For these reasons, the Court should affirm the judgment below.

CONCLUSION

For the reasons set forth above and in respondent's brief, the judgment below should be affirmed.

Respectfully submitted,

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August 14, 2008